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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,177	01/29/2001	Ake Lindahl	003300-696	2132

35437 7590 05/10/2005

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/700,177	<b>Applicant(s)</b> LINDAHL ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 57,58,60-84 and 86-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57,58,60-84 and 86-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

20

### **DETAILED ACTION**

Examiner acknowledges receipt of revocation of power of attorney filed 01/12/05, request for extension of time and remarks filed 03/18/05, request for continues examiner under 37 CFR 1.114 and request for extension of time filed 04/12/05. Claims 57, 58, 60-84, 86-106 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 04/12/2005 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 57, 58, 60-84, 86-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While chemical reaction may be understood to mean chemical

Art Unit: 1618

transformation, interaction of chemical entity or the change in atomic nuclei, dependent claims 60 and 88 define chemical reaction as etherification, esterification, hydrolysis, substitution, addition, elimination, oligomerization or polymerization. However, the specification/written description does not describe how a carrier undergoes a chemical reaction in the invention.

5. Claims 57, 58, 60-84, 86-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 is directed to a method of preparing a biologically active composition where the method comprises (a) supplying a composition that includes one or more starting substance, (b) chemically reacting the composition of step a over a period of time to form or cleave ... and (c) adding the biologically active agent to the composition .... But when the composition in step a is recited as one carrier, it is not clear how that can be a composition. In step 2, what is being reacted with the one carrier?

Claim 75 recites that methacrylate is an acrylamide compound and it is not clear how methacrylate can be an acrylamide compound since acrylamide is an amide and methacrylate is the methyl substituted acrylic acid and not an amide.

Claim 94 is confusing.

### ***Claim Objections***

6. Claims 73, 74, 78-80 do not further limit the method of claim 57 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place

Art Unit: 1618

the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. For example, claim 78 recites the properties of melanocyte stimulants and gland stimulants.

7. Claims 95-97 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 95-97 do not further limit the process of claim 87.

The claims are examined as the process of preparing biologically active composition, the method comprises incubating biologically active agent with the one carrier and during the incubation period, a chemical reaction occurs between the carrier and the biological agent. The above interpretation is applicable to claims 57 and 87.

The following art rejection is made on the basis of the interpretation.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 57, 58, 61, 62, 64-75, 78-84, 86, 87, 89-97, 100-102 and 105 rejected under 35 U.S.C. 102(e) as being anticipate by Farinas et al. (US 5,906,830).

Farinas discloses a method for preparing transdermal drug delivery systems containing supersaturated drug reservoirs (abstract). The drug is heated to a temperature just higher than the calculated depressed melting temperature (column 6, lines 12-21). Farinas discloses that an

Art Unit: 1618

amount of drug molecule is dispersed in the reservoir material at a concentration that is greater than the solubility of the drug in the reservoir material at room temperature to give a supersaturated drug reservoir (column 5, lines 1-10). The components of the reservoir include polymeric materials selected from polysiloxanes, polyacrylates and polyurethane adhesives (column 6, line 61 to column 7 line 24). Drugs that may be incorporated in the drug delivery system are narcotic agonists and antagonists, serotonergic agonists, antihistamines, anti-inflammatory agents, benzodiazepines, dopaminergic agonists and antagonists, hormones and antipsychotic agents (column 7, lines 39-64). The drug formulation further includes carriers or vehicles selected from stabilizers, antioxidants, anti-irritants, cellulosic polymers, polyvinyl alcohol and polyacrylic acid. See also claims 1-14.

The method of Farinas comprises mixing polymeric material and a drug formulation, removing the most of the solvent, evaluating the depressed melting temperature of the drug-polymer mixture, heating the mixture to a predetermined temperature and cooling the heated mixture to form the supersaturated reservoir (claim 1). The invention does not specifically state a teaching of chemical reaction. However, chemical reaction, as the Examiner interprets the claims, takes place when the biologically active agent and the carrier are incubated and the result of the incubation is the formation of a composition that comprises the carrier and the active agent. The method of Farinas also includes a heat step. Farinas thus anticipates the claims.

***Claim Rejections - 35 USC § 103***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1618

11. Claims 60, 63, 76, 77, 88, 98, 99, 103, 104 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farinas et al. (US 5,906,830).

Farinas is described above. Farinas is silent on the processes recited in claims 60 and 88. However the designated claims do not say how those processes came to be or the agents that aid in the reaction to bring about the process. It is however interpreted that the chemical reaction occurs when the active agent is incubated with a carrier. And since Farinas mixes a carrier and an active agent and the process of mixing necessarily incorporates a wait or incubation period that is not specifically disclosed by Farinas. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition that comprises a carrier and bio-active agent by incubating the carrier and the bio-active agent for some determined time. One having ordinary skill in the art would have been motivated to incubate the carrier and the bioactive agent for a predetermined time with the expectation of producing bioactive composition comprising a drug and a carrier. Incubating the carrier and the bioactive agent for 1 minute to 6 months is not inventive over the prior art in the absence of a showing.

#### ***Response to Arguments***

12. Applicants' arguments filed 03/18/05 have been fully considered but they are not persuasive. With regards to applicants' argument that Farinas does not teach a chemical reaction, it is respectfully noted that the chemical reaction in the instant application involves the incubation of a biologically active agent with a carrier or with two or more carriers. In this respect, Farinas discloses a chemical reaction. As pointed to above, a reaction such as elimination or etherification or esterification would require agents besides one carrier and

Art Unit: 1618

biologically active agent. Examiner agrees with applicants that every input of energy does not lead to chemical reaction except those that are dependent on heat to lower the energy barrier to make the "latent reaction" to proceed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following art are of approximate relevance as Farinas.

Lindahl (WO 97/00670, cited in the instant specification) discloses a process of preparing biologically active composition by combining glass-forming carrier and biologically active agent (abstract).

Poile (GB 2 306 885, cited in the instant specification) discloses method of preparing biologically active composition by incubating pharmaceutically active agent and carrier vehicle (abstract).

Farinas et al. (WO 97/10812, cited in applicants' specification) discloses a method of preparing a composition comprising active agent and carrier (abstract).

Note:

Formation of covalent bond is not the same as breaking a covalent bond. While the formation/creation of a covalent bond may involve the breaking of covalent bond, the process of forming a covalent bond differs from the process of breaking the bond.

The processes of etherification, esterification, hydrolysis, substitution, addition, elimination, oligomerization or polymerization do not necessarily produce equivalent products.



Art Unit: 1618

14. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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